UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JANSSEN SCIENCES IRELAND UNLIMITED COMPANY, *et al.*,	:	
Plaintiffs,	:	**MEMORANDUM DECISION AND ORDER**
- against -	:	22-cv-1983 (BMC)
TLC XPRESS PHARMACY INC., *et al.*,	:	
Defendants.	:	

COGAN, District Judge.

Over the past several years, civil plaintiffs and government prosecutors alike have sought to hold accountable the participants of a nationwide drug counterfeiting conspiracy. Plaintiffs here, component entities of a pharmaceutical conglomerate, brought this action against various downstream distributors that allegedly sold the counterfeit medication. Before the Court are plaintiffs' motion and the remaining defendants' cross-motions for summary judgment. Plaintiffs' motion is granted in part and denied in part, and defendants' motions are denied.

In short, there are genuine issues of material fact precluding summary judgment on all but three discrete issues in this case. Plaintiffs are entitled to judgment as a matter of law that certain bottles are not genuine products, and therefore would infringe on their trademarks if sold; that any ingenuine bottles are also counterfeits; and that the individual defendants' Lanham Act liability coextends with the defendant companies' Lanham Act liability. But issues of fact remain as to whether all the identified bottles are infringing, how many of the infringing bottles defendants sold, and whether defendants acted willfully.

BACKGROUND

Plaintiffs Janssen Sciences Ireland Unlimited Company; Janssen Products, L.P.; and Johnson & Johnson (collectively, "Janssen") develop and market a laundry list of medications. Janssen holds trademark registrations for many of the medications it manufactures, and it generally adds these marks, alongside its own "Janssen" mark, to the medications' labels.

In November 2020, pharmacies and patients began complaining to Janssen about receiving bottles of "Symtuza," a Janssen-trademarked HIV medication, that contained "Prezcobix," a different Janssen-trademarked HIV medication. Janssen launched an investigation in response and uncovered that several pharmacies were dispensing bottles with similar defects. It was able to trace the defective bottles back to three wholesalers, which it then sued, initiating the instant action.

After another drug manufacturer, Gilead, launched a similar civil suit against the wholesalers and the Department of Justice began related criminal proceedings, the full conspiracy came into picture. At its center were illicit suppliers who would pay patients cash for their prescription medications, repackage the pills, falsify documents to cover their tracks, and then resell the medications to the wholesalers at a generous discount. The wholesalers would eventually sell the drugs to pharmacies, at which point patients would receive the black-market-sourced bottles.

Aided by this Court's discovery orders, Janssen recovered thousands of its bottles it contends passed through the black market. Some bottles were missing "outserts," *i.e.*, FDA-required instructions for use that Janssen folds and glues to the outside of each bottle. Some bottles had inauthentic caps. Some bottles had scratches on their labelling that obscured various

identifying information, such as 2D matrix codes, lot numbers, and expiration dates. And, of course, some bottles contained incorrect pills.

All the bottles, though, had one thing in common – falsified or missing pedigrees. The Federal Food, Drug, and Cosmetic Act ("FDCA") requires that drug manufacturers, distributors, and dispensers maintain a so-called pedigree for each prescription medication it sells. A pedigree contains three pieces of information: the drug's chain of custody, or its "transaction history"; the details of each sale, or its "transaction information"; and a formal transfer of ownership, or a "transaction statement." 21 U.S.C. §§ 360eee(25)-(27), 360eee-1. Manufacturers electronically transmit these pedigrees to their distributors, who then update the information and pass the pedigree down the supply chain as the correlative medication is sold and resold.

Janssen first brought this suit against only the wholesalers, who have since settled the claims against them. It later amended its complaint to add, among other parties who followed the wholesalers' lead, the remaining defendants: Cina Pharmaceuticals, Inc., a pharmaceutical distributor, and its principal Tronown Thomas (collectively, the "Cina defendants"); SRX Specialty Care Pharmacy, a pharmacy, and its principal Aman Deep Singh (collectively, the "SRX defendants"); and TLC Xpress Pharmacy Inc., another pharmacy, and its principal Kevin Nhathuy Quang Tran (collectively, the "TLC defendants"). The amended complaint asserts a Lanham Act trademark-infringement claim and six related causes of action.

Janssen now moves for summary judgment on liability for the Lanham Act claim against the remaining defendants. It also seeks summary judgment on two related issues: (1) that Cina and Thomas willfully infringed on its trademark, and (2) that the identified bottles are

"counterfeits." SRX, TLC, Cina and their principals filed a cross motion for summary judgment on all claims against them.

DISCUSSION

I. Summary Judgment Standard

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court must "construe the facts in the light most favorable to the non-moving party and must resolve all ambiguities and draw all reasonable inferences against the movant." Brod v. Omya, Inc., 653 F.3d 156, 164 (2d Cir. 2011). To prune a case in advance of trial, a court may grant partial summary judgment on freestanding, non-dispositive issues. See Fed. R. Civ. P. 56(g).

"Cross-motions for summary judgment do not alter the basic standard, but simply require the court to determine whether either of the parties deserves judgment as a matter of law on facts that are not in dispute." AFS/IBEX v. AEGIS Managing Agency Ltd., 517 F. Supp. 3d 120 (E.D.N.Y. 2021). "[E]ach party's motion must be examined on its own merits, and in each case all reasonable inferences must be drawn against the party whose motion is under consideration." Morales v. Quintel Ent., Inc., 249 F.3d 115 (2d Cir. 2001).[1]

II. Trademark Infringement

The Lanham Act prohibits the "use in commerce," without a trademark holder's consent, of "any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection

[1] Defendants ask me to strike Janssen's submitted Rule 56.1 statement for failing to comply with the Court's Individual Practice Rules. They accuse Janssen of listing "multiple facts per paragraph" and describing evidence rather than simply stating material facts. I would be far more inclined to grant this request if defendants' Rule 56.1 statements didn't also list multiple facts per paragraph and describe evidence. Instead, exercising my broad discretion, I decline to strike any portion of Janssen's filing. See Mayaguez S.A. v. Citigroup, Inc., No. 16-cv-6788, 2021 WL 1799653, at *6 (S.D.N.Y. April 30, 2021).

with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive." 15 U.S.C. § 1114(1)(a). Conspicuously absent from the Lanham Act's prohibition on trademark infringement is any sort of mental-state requirement; trademark infringement is a strict-liability offense, and thus a plaintiff "need not prove knowledge or intent." Spin Master Ltd. v. Alan Yuan's Store, 325 F. Supp. 3d 413, 421 (S.D.N.Y. 2018). A showing of willfulness triggers enhanced damages, as discussed more thoroughly below, but it is not necessary to establish liability.

To determine whether an alleged use of a mark is likely to cause confusion, the Second Circuit generally applies the eight-factor test outlined in Polaroid Corp. v. Polarad Electronics Corp., 287 F.2d 492 (2d Cir. 1961). However, courts need not trudge through the Polaroid factors when, like here, infringement claims target "trademarked domestic goods sold by unauthorized retailers." Coty Inc. v. Cosmopolitan Cosms. Inc., 432 F. Supp. 3d 345, 351 (S.D.N.Y. 2020); see also Zino Davidoff SA v. CVS Corp., 571 F.3d 238, 242-43 (2d Cir. 2009); Polymer Tech. Corp. v. Mimran, 37 F.3d 74 (2d Cir. 1994). This makes sense. The Polaroid factors mainly guide courts in determining whether the use of an "imitative" mark constitutes trademark infringement, see Polaroid, 287 F.2d at 495-96, and that question is irrelevant when defendants admit they used the plaintiff's actual mark.

Rather, the relevant question is whether the trademarked goods sold were "genuine." See Original Appalachian Artworks, Inc. v. Granada Elecs., Inc., 816 F.2d 68, 73 (2d Cir. 1987). If defendants sold "genuine goods bearing a true mark," they did not run afoul of the Lanham Act. Polymer Tech. Corp. v. Mimran, 37 F.3d 74, 78 (2d Cir. 1994). Conversely, if the goods were somehow ingenuine, defendants are liable for trademark infringement. Id. Two categories of

ingenuine goods are relevant here: goods that "differ materially from the product authorized by the trademark holder for sale" and goods that "do not conform to the trademark holder's quality control standards." Zino Davidoff, 571 F.3d at 243. In either case, the seller's use of the mark is likely to cause confusion and therefore constitutes trademark infringement.

Janssen advances multi-layered accusations against defendants under this framework. At the broadest level, Janssen alleges that each identified bottle infringes on its mark because they were all sold without valid pedigrees. The invalid pedigrees, in Janssen's view, both render the products materially different and interfere with its quality-control standards. Janssen further alleges that the bottles with missing outserts, damaged labels, fake caps, and incorrect pills are similarly materially different and violative of its quality-control policies. I address first the broader theory and hold that, although invalid pedigrees are not material differences, there are triable issues as to whether selling drugs with missing and falsified pedigrees violate Janssen's quality-control standards. I then turn to the narrower theories, on which I also find triable issues.

A. Bottles with Erroneous Pedigrees

i. Material Differences

As a preliminary matter, I cannot conclude that a bottle distributed with inaccurate or missing pedigrees is "materially different" from a bottle distributed with genuine pedigrees, despite Janssen's arguments to the contrary. A material difference is a "difference that consumers would likely deem relevant when considering a purchase of the product." Abbott Lab'ys v. Adelphia Supply USA, No. 15-cv-5826, 2015 WL 10906060 at *6 (E.D.N.Y. Nov. 6, 2015), aff'd sub nom. Abbott Lab'ys v. H&H Wholesale Servs., Inc., 670 F. App'x 6 (2d Cir. 2016). Accordingly, although courts apply a "low threshold of materiality," the difference must relate to some characteristic of the product that is relevant to a consumer. Id. The difference

need not be tangible. See Dan-Foam A/S v. Brand Named Beds, LLC, 500 F. Supp. 2d 296, 310-11 (S.D.N.Y. 2007). But, again, it must be a "difference in the product itself." Original Appalachian, 816 F.2d at 68.

Invalid pedigrees are quite simply not such a material difference. Holding all else equal, a medication with missing or falsified pedigrees has the exact same packaging, labelling, and pills as a medication with accurate pedigrees. The trademarked good – the medication – is not any less appealing to a consumer. Cf. Zino Davidoff, 571 F.3d at 246 (holding that luxury fragrances with damaged labels were materially different from the genuine product). Nor does it lack some intangible benefit, like a warranty. Cf. Dan-Foam, 500 F. Supp. 2d at 311 (holding that a mattress without a warranty is materially different from a mattress with a warranty). Indeed, patients do not even receive pedigree information.

Janssen nevertheless insists that the medications are materially different because pharmacists and distributors do receive pedigrees, and "every pharmacist whose statement appears in the record" testified "that they would not purchase or dispense Janssen-branded products if they knew the products were sourced from unlicensed black-market suppliers." Ergo, it concludes, the falsified pedigrees are a material difference.

This logic has two fatal defects. First and most fundamentally, Janssen gets the material-difference inquiry exactly backwards. We must determine whether a product is materially different because unauthorized distribution, standing alone, cannot constitute trademark infringement. See, e.g., Polymer Tech. Corp., 37 F.3d at 80; Original Appalachian Artworks, Inc. v. Granada Elecs., Inc., 816 F.2d 68 (2d Cir. 1987). The prospect of unauthorized distribution itself cannot be a material difference.

Second, Janssen has provided no evidence that a retailer would assume that a product with inaccurate or missing pedigrees was distributed through black-market channels. Take, for example, a medication distributed in the normal course through Janssen's authorized distributors. If a distributor mistypes the date in the transaction history section, or misattributes the name of next purchaser in the transaction information section, does the purchaser receive a drug that is in any way different from a drug distributed with accurate pedigrees? Janssen provides a jury with no reason to believe such an error would reflect on Janssen and its trademarked product rather than the distributor.

Requiring that a "material difference" relate to some quality of the trademarked good is not a novel concept. Every material-difference case cited by the parties, and to boot every material-difference case that the Court is aware of, considered differences in the product itself, its packaging, or some intangible benefit enjoyed by a purchaser of the product. See, e.g., Original Appalachian 816 F.2d at 73; Coty, 432 F. Supp. 3d at 351; Dan-Foam, 500 F. Supp. 2d at 311. By contrast, the cases involving differences some formal process separate from the product sold, like pedigrees, focus on quality control. See, e.g., Warner-Lambert Co. v. Northside Dev. Corp., 86 F.3d 3 (2d Cir. 1996)

ii. Quality Control

Janssen's pedigree theory fares much better when viewed as a claim that the sales do not conform to Janssen's quality-control standards. To prevail on quality-control grounds, a Lanham Act plaintiff must show that "(i) it has established legitimate, substantial, and nonpretextual quality control procedures, (ii) it abides by these procedures, and (iii) the non-conforming sales will diminish the value of the mark." Warner-Lambert, 6 F.3d at 6. The frustration of a system

that allows a plaintiff "to detect and prevent the sale of counterfeits" constitutes trademark infringement. Zino Davidoff, 571 F.3d at 244.

Janssen has adduced enough evidence to create issues of material fact on all three elements. On the first element, Janssen submits that it has a policy of keeping accurate pedigree information and that this policy is legitimate and substantial because Janssen "request[s] pedigrees" whenever it "is informed of a suspect product incident" so it can "evaluate [a] product's chain of custody and whether the listed companies are legitimate." Additionally, Janssen relies on pedigree information "to expedite recalls in the event of any problems with the health, safety or integrity of its products." Gilead Scis., Inc. v. Safe Chain Sols., LLC, 684 F. Supp. 3d 51, 67 (E.D.N.Y. 2023) (quoting Monsanto Co. v. Haskel Trading, Inc., 13 F. Supp. 2d 349, 357 (E.D.N.Y. 1998)).

Defendants cast doubt on whether Janssen established a legitimate and non-pretextual procedure, but not enough doubt to preclude a reasonable jury from disagreeing with them. They point to Janssen's written quality control policies, which mention pedigrees only in an example. Although that might counsel against finding for Janssen, it does not preclude judgment for it as a matter of law. The Second Circuit has recognized that quality-control policies need not be in writing to be bona fide. See Warner-Lambert, 86 F.3d at 7. Similarly, defendants fault Janssen for failing to require that downstream distributors transmit pedigree data. But the Second Circuit has held that a manufacturer need not enforce its own quality control measures on downstream purchasers with whom it has no contractual relationship. Id. And, obviously, there is good reason why Janssen doesn't formally require its purchasers to maintain accurate pedigree information – the FDA already does.

On the second element, the parties supply conflicting evidence that Janssen in fact follows this policy. Janssen submits testimony that it "requested and relied on pedigrees to investigate the very wrong-pill counterfeits that gave rise to this case," while Cina claims that Janssen follows the same investigative procedures regardless of whether it receives transaction data. Finally, on the third element, there is a genuine issue as to whether Janssen's mark is harmed by non-conforming sales. A reasonable jury could, but need not, conclude that the sale of drugs without accurate pedigrees increases the chances that counterfeits are sold. See Gilead Scis., 684 F. Supp. 3d at 67.

Cina asks us to reject Janssen's quality-control theory as overbroad. "If a failure to transmit transaction data interferes with Janssen's quality control standards," it argues, "so too does a pharmacist who misplaces an invoice" and so too does "a *patient* who refuses to speak with Janssen's investigators." This non sequitur does not persuade. A pharmacist would not be liable for selling misplacing an invoice unless Janssen can establish that it follows a legitimate, non-pretextual, invoice-retention policy and that the pharmacist's failure to follow this policy impacts the value of its mark. A patient, on the other hand, does not even use the mark in commerce.

iii. Nominative Fair Use and Preclusion

Before I conclude that Janssen's pedigree-based infringement claim can proceed to trial, I must address two broad shields raised by defendants. The SRX and TLC defendants argue that their sales fall within the "nominative fair use" doctrine, and the Cina defendants argue that the FDCA precludes Janssen's claim.

I address first nominative fair use. "The doctrine of nominative fair use allows a defendant to use a plaintiff's trademark to identify the plaintiff's goods so long as there is no

likelihood of confusion about the source of the defendant's product or the mark-holder's sponsorship or affiliation." Tiffany (NJ) Inc. v. eBay Inc., 600 F.3d 93, 102 (2d Cir. 2010) (cleaned up). The doctrine recognizes the straightforward principle that "a defendant may lawfully use a plaintiff's trademark when doing so is necessary to describe the plaintiff's product and does not imply a false affiliation or endorsement by the plaintiff of the defendant." Id. The Second Circuit has instructed district courts to consider certain nominative-fair-use factors alongside the Polaroid factors in applicable cases. See Int'l Info. Sys. Sec. Certification Consortium, Inc. v. Sec. Univ., LLC, 823 F.3d 153, 168 (2d Cir. 2016).

Yet the Second Circuit has never looked to the nominative-fair-use factors in a quality-control case, and for good reason. Like the Polaroid factors, the doctrine of nominative fair use collapses into a genuineness analysis when a defendant admits to using the plaintiff's mark to sell, what at least the defendant contends is, the plaintiff's genuine product. If defendants impeded Janssen's right to control the quality of its trademarked goods, they "impl[ied] a false affiliation or endorsement." Tiffany (NJ), 600 F.3d at 102. If they did not, then they are protected by the doctrine of nominative fair use. At least on this record, there is no space between the nominative-fair-use and infringement questions.

I am similarly unmoved by the Cina defendants' argument that Janssen's pedigree claim is precluded by the FDCA. It is true that "all … proceedings for the enforcement, or to restrain the violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Yet the Supreme Court has recognized that § 337(a) does not *per se* preclude Lanham Act claims targeting products subject to FDCA regulation. POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102 (2014)). It has held that § 337(a) does not preclude Lanham Act claims "in situations when the FDCA or the FDA, through its regulations, have 'specifically require[d] or

authorize[d]' a challenged aspect of a regulated product." Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH, 843 F.3d 48, 63 (2d Cir. 2016) (alterations in original) (quoting POM Wonderful, 573 U.S. at 119).

Because no Supreme Court or Second Circuit case has addressed exactly when the FDA *does* preclude a Lanham Act claim, the Cina defendants ask me to apply a rule developed by the Federal Circuit in Amarin Pharma, Inc. v. Int'l Trade Comm'n, 923 F.3d 959 (Fed. Cir. 2019). Amarin held that "at least until the FDA has provided guidance," the FDCA precludes claims "based on proving violations of the FDCA . . . where the FDA has not taken the position [on] the articles." Id. at 968 (cleaned up).

Setting aside whether the Second Circuit would follow suit, I can assume without deciding the Amarin framework applies because Janssen's Lanham claims would still fall outside of § 337(a). The claims are not "based on proving violations" of the pedigree requirements. Defendants acknowledge that the pedigrees here are noncompliant with the applicable regulations, and thus no party is asking the court to determine whether defendants, or any other supplier, violated the FDCA. I need only decide whether Janssen employed quality-control policies that relied on downstream distributors maintaining accurate pedigrees. In fact, the pedigree issue is undisputed because this is the exact scenario the Amarin court recognized might solve a preclusion issue. By criminally prosecuting the illicit suppliers, the United States has "provided guidance" as to whether the pedigree requirements were violated. It emphatically said that they were.

Assured that the trademark-infringement claims are neither barred by the doctrine of nominative fair use nor precluded by the FDCA, I can deny defendants' motions for summary judgment as to liability.[2] The claims shall proceed to trial.

B. Other Bottles

As a fallback, Janssen also seeks summary judgment on its narrower theories of infringement targeting only a select few bottles it recovered. It identifies bottles with missing or fake outserts, visibly damaged labels, different caps, and most seriously, wrong pills. I have no trouble concluding as a matter of law that these bottles are materially different from the genuine medications. However, I cannot grant summary judgment to Janssen even on these limited grounds because triable issues remain as to whether defendants are liable for selling them.

Take first the bottles with missing or fake outserts. Janssen has provided undisputed evidence that its FDA-approved outserts list instructions for use, common and serious side effects, and drug interactions. This renders the bottles materially different from the originals. See e.g. Johnson & Johnson Consumer Companies, Inc. v. Aini, 540 F. Supp. 2d 374, 387 (E.D.N.Y. 2008). "A consumer may decide not to purchase the product after reading that it could" lead to certain side effects or interact with other drugs the consumer is taking. Id.

The same is true of the bottles with visibly damaged labels. The Second Circuit has made clear that "[m]utilation of packaging to conceal markings may lead the consumer to suspect that the item is stolen merchandise, or is defective and has been diverted from a recall, or is otherwise untrustworthy." Zino Davidoff, 571 F.3d at 246. Each of the labels here has a

[2] Because I find that there are issues of fact precluding summary judgment on the trademark claim, defendants are not entitled to summary judgment on any of the related claims. As they acknowledge, most of the other claims are "premised on the infringing nature of [the] products." And, to the extent defendants propose independent grounds for summary judgment on some of those claims, their arguments are "skeletal" at best and do not warrant my consideration. Alberti v. County of Nassau, 393 F. Supp. 2d 151, 162, n. 1 (E.D.N.Y. 2005).

mutilated 2D matrix or similar identification marking. Cina counters that "Janssen has not shown that consumers understand the import of a 2D matrix or the bottle's identifying information." Yet Zino Davidoff rejected that argument, reasoning that "[w]hether Davidoff's retailers and consumers [were] aware of how to obtain information from the" identifying markings at issue there was "of no significance." Id. at 245. Visibly marred identifying information is a "slight difference" that consumers would consider when evaluating Janssen's product. Abbott Lab'ys, 2015 WL 10906060 at *6.

I similarly have no trouble concluding that the bottles with the incorrect pills and different caps are materially different. No defendant dared dispute that the pills within a bottle would be relevant to a patient prescribed the medication. And a patient could very well prefer one cap to another, or believe that one cap appears more clean, professional, and safe. This satisfies, as a matter of law, the "low threshold of materiality." Id.

All that said, there are still material facts precluding me from granting Janssen's motion in full. For starters, defendants offer plausible rationales that separate them from the wrong-pill bottles. The SRX and TLC defendants point out that Janssen has since discovered an issue on its production line and that Symtuza and Prezcobix were manufactured on the same production line. In a similar vein, the Cina defendants cast doubt on the credibility of the patient who reported that one of Cina's bottles contained a wrong pill. These rationales are tenuous at best, and I have a particularly hard time believing that a jury would discredit the testimony of an HIV-positive patient, especially considering that the bottle's pedigrees were falsified. But I cannot make such a credibility determination at this stage.

Further, in its inventory database available to purchasers, Cina designated at least some of the identified bottles as damaged. Relying on the principle that when a "defendant sufficiently

discloses the existence of the difference alleged to be material . . . the possibility of confusion arising from the difference is dispelled," the Cina defendants argues that this disclosure immunizes them from Lanham Act liability. See Bel Canto Design, Ltd. v. MSS Hifi, Inc., 837 F. Supp. 2d 208, 224 (S.D.N.Y. 2011). Janssen makes no effort to dispute this. I therefore assume, without deciding, that the sale of any bottle classified as "damaged" does not infringe on Janssen's mark.

I am nevertheless reluctant to undertake a fact-bound inquiry into which identified bottles were given a DMG classification. Instead, having found at least one material issue of fact, I exercise my discretion to deny summary judgment to both sides. See D'Iorio v. Winebow, Inc., 68 F. Supp. 3d 334, 356 (E.D.N.Y. 2014) (citing Fed. R. Civ. P. 56(g)). A jury will determine which bottles defendants are liable for selling.

C. Individual Liability

There is one more infringement-related issue I must address. Janssen seeks summary judgment that the individual defendants' liability is coextensive with their respective employers. Its motion is granted on this issue.

When a business entity infringes on a trademark, the Lanham Act holds liable any individual who was a "moving, active[,] conscious force behind" the infringing conduct. Abbott Lab'ys, No. 15-cv-5826, 2019 WL 5696148 at * 16 (first alteration in original) (quoting Innovation Ventures, LLC v. Ultimate One Distrib. Corp., 176 F. Supp. 3d 137, 155 (E.D.N.Y. 2016)). "A corporate officer is considered a moving, active, conscious force behind a company's infringement when the officer was either the sole shareholder and employee, and therefore must have approved of the infringing act, or a direct participant in the infringing activity." Innovation Ventures, 176 F. Supp. 3d at 155 (cleaned up). "[I]t is immaterial whether" the individual

defendant "knows that his acts will result in an infringement." KatiRoll Co. v. Kati Junction, Inc., 33 F. Supp. 3d 359, 367 (S.D.N.Y. 2014) (quoting Bambu Sales, Inc. v. Sultana Crackers, Inc., 683 F. Supp. 899, 913 (E.D.N.Y. 1988)).

There are three individual defendants remaining: Tronown Thomas – Cina's owner, president, and sole director; Aman Deep Singh – SRX's owner and "pharmacist in charge"; and Kevin Nhathuy Quang Tran – TLC's principal and lead pharmacist. Because it is undisputed that no individual defendant was the sole shareholder and employee of the company defendants, individual liability turns on whether they were "direct participants" in the infringing activities.

Janssen has set forth substantial evidence that each individual directly participated in the purchase and sale of the bottles. Cina's Rule 30(b)(6) witness testified that "Mr. Thomas handled everything" with respect to Cina's suppliers. An order form shows that Singh personally placed purchase orders with SRX's suppliers. And emails suggest that Tran was the sole user of tlcxpress@yahoo.com, the address that TLC used to buy and sell medication.

Defendants do not provide any evidence controverting the inference that the individual defendants directly participated in the purchase and sales of the identified medications. Their replies are focused on whether the individual defendants knew, or should have known, that the products were counterfeit. For instance, the TLC and SRX defendants offer only that Tran and Singh "were likely to be confused that the products they were buying . . . were somehow counterfeit and/or not authentic." This fact is relevant, but to willfulness, not liability. For liability purposes, Janssen need only show that the pharmacists directly participated in the sale of infringing goods, and defendants have provided no facts to the contrary. Accordingly, Janssen's motion is granted, and defendants' motions are denied, on individual liability

III. Damage Enhancements

I finally turn to the counterfeit and willfulness issues. In addition to its general strict-liability prohibition on trademark infringement, the Lanham Act provides enhanced penalties for certain types of infringement. It allows a plaintiff to recover more when a defendant willfully infringes on a trademark. Island Software & Computer Serv., Inc. v. Microsoft Corp., 413 F.3d 257, 263 (2d Cir. 2005). It also provides special monetary remedies when a defendant "intentionally us[es] a . . . counterfeit mark." 15 U.S.C. § 1117(b)(1). The amended complaint alleges that all remaining defendants acted willfully and that all the bottles are counterfeits. Janssen moved for summary judgment on the Cina defendants' willfulness and on the counterfeit score.

A. Willfulness

The Second Circuit has recognized two ways to prove "willfulness" under the Lanham Act. A plaintiff can show that the defendant had actual knowledge – *i.e.*, that "the defendant was actually aware of the infringing activity." Island Software, 413 F.3d at 263 (cleaned up). Or a plaintiff can show that the defendant acted with "reckless disregard or willful blindness" – *i.e.*, "that [the] defendant knew it might be selling infringing goods but nevertheless 'intentionally shielded itself from discovering' the truth." Fendi Adele, S.R.L. v. Ashley Reed Trading, Inc., 507 F. App'x 26, 31 (2d Cir. 2013) (quoting Tiffany (NJ) Inc. v. eBay Inc., 600 F.3d 93, 109 (2d Cir. 2010)). Willfulness "can be proven on summary judgment." Id.

To its credit, Janssen provides weighty evidence that the Cina defendants knew, or at the very least were willfully blind to the fact that, Cina was purchasing black-market medicine. It highlights that Cina purchased drugs at a near 80% discount from the wholesale price, that Cina failed to follow its own supply-chain-integrity policies, and that Cina was warned about doing business with certain suppliers.

Whether Janssen established willfulness, however, is a question for the jury. Cina has responded with plenty of evidence suggesting that, at worst, it was negligent in selling any allegedly infringing bottles. Thomas testified that the company "inspected every medication sold to it and ensured it was in good condition, had an outsert, had a standard cap, and was sealed." If any medication "failed this inspection," he went on, it "was placed in either quarantine or the DMG category."

Perhaps realizing the record contains at least some conflicting evidence on whether Thomas was willfully blind, Janssen insists that I am bound to infer he had actual knowledge of the infringing sales. It reasons that because Thomas invoked his Fifth Amendment right against self-incrimination when asked whether he knew about the allegedly infringing activities, I must make "an adverse inference" against him. Janssen is right that a civil litigant who "asserts the privilege against self-incrimination must bear the consequence of lack of evidence, and the claim of privilege will not prevent an adverse finding or even summary judgment if the litigant does not present sufficient evidence to satisfy the usual evidentiary burdens in the litigation." Louis Vuitton Malletier S.A. v. LY USA, Inc., 676 F.3d 83 (2d Cir. 2012). But Cina has provided enough counter evidence that a reasonable jury could still find a lack of willfulness despite the adverse inference.

Less convincing still is Janssen's request for an adverse inference based on Thomas's deletion of certain text messages with Cina's suppliers, including the supplier of one of the alleged wrong pill bottles. To acquire an adverse inference for spoliation grounds, Janssen must demonstrate that Thomas had a duty to retain the texts, that he had a culpable state of mind, and that the information would be relevant to Janssen's case. See Byrnie v. Town of Cromwell, 243 F.3d 93, 107 (2d Cir. 2001), superseded on other grounds by Fed. R. Civ. P. 37(e) (2015).

Janssen has not explained why Thomas had a duty to preserve the texts, has not pointed to any evidence suggestive of a culpable state of mind, and admits that it acquired the texts from other sources. The cross-motions are denied on the issue of willfulness.

B. Counterfeiting

A counterfeit mark is "a spurious designation that is identical with, or substantially indistinguishable from" a bona fide mark. 15 U.S.C. § 1116(d)(1)(B). Yet the Lanham Act exempts "any mark or designation used on or in connection with goods or services of which the manufacture or producer was, at the time of the manufacture or production in question authorized to use the mark or designation for the type of goods or services so manufactured or produced." Id. These definitions lead us back to familiar territory. Like in the infringement context, goods sold with a true mark are not counterfeits unless are somehow "changed so as to deceive buyers." 3 Thomas J. McCarthy, McCarthy on Trademarks and Unfair Competition, § 25:15 (citing U.S. v. Milstein, 401 F.3d 53, 63 (2d Cir. 2005)).

Janssen argues that, for the same reasons the bottles are infringing, they are also counterfeits. Although defendants of course vigorously dispute that the bottles are infringing, they do not seriously argue that the bottles might possibly infringe but still fall outside of the Lanham Act's definition of a counterfeit. And I am satisfied that Janssen is right. The Second Circuit has not squarely addressed the issue, but courts in this circuit have applied the "test for genuineness," the same test I applied above, to determine whether trademarked domestic goods sold by unauthorized retailers are counterfeits. Coty Inc. v. Cosmopolitan Cosms. Inc., 432 F. Supp. 3d 345 (S.D.N.Y. 2020) (quoting Johnson & Johnson Consumer Cos. v. Aini, 540 F. Supp. 2d 374, 385 (E.D.N.Y. 2008)); see also Tiffany and Co. v. Costco Wholesale Corp., 13-cv-1041,

2019 WL 120765, at *8 (S.D.N.Y. Jan. 7, 2019). Thus, to the extent the bottles infringe on Janssen's trademark, they are counterfeits.

CONCLUSION

Janssen's motion is GRANTED in part and DENIED in part, and defendants' cross-motions are DENIED. Janssen is entitled to summary judgment on three discrete issues: that the damaged bottles infringe on its trademark, that any infringing bottles are also counterfeits, and that the individual defendants are liable to the same extent as the defendant companies. There are genuine issues of material fact as to whether all the bottles are infringing, whether defendants acted willfully, and whether the infringing bottles were sold by defendants.

SO ORDERED.

Brian M. Cogan
U.S.D.J.

Dated: Brooklyn, New York
April 1, 2025